REMARKS

The Applicant has carefully reviewed the Office Action dated December 9, 2009 relating to the subject patent application. Based on the foregoing claim amendments and the following remarks, the Applicant submits that the pending claims are in condition for allowance. Reconsideration of the amended claims and issuance of a notice of allowance are respectfully requested.

Status of the Claims

Claims 1-25 were pending in this patent application. Claims 15-25 were previously withdrawn from consideration in response to a restriction requirement. Claims 1-14 are currently pending. Claims 1, 9 and 10 are amended for clarification. Support for the amendment can be found in the specification as originally filed (see, for example [0026]). Claims 1-14 are rejected in the above-mentioned Office Action.

Claim Rejections Under 35 U.S.C. 112

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner asserts that the recitation of the phrase "complement C4d associated with platelets" in claim 1 is vague and indefinite because it is unclear what is encompassed in the recitation of "associated with". The Applicant respectfully disagrees. The Applicant submits that the term "associated with" is defined in the originally filed specification. See paragraph [0019] wherein it states as follows.

> "For accuracy, the methods described herein measure C4d "associated with" platelets. The reason for this distinction arises from the fact that some methods, such as flow cytometry, measure C4d on the surface of intact platelets directly, while other methods quantitate surface C4d indirectly in a sample of disrupted platelets, and do not literally measure C4d on the surfaces of platelets. As such, as used herein, C4d is said to be "associated with" platelets, which means either C4d is on the surface of a platelet or it is present in a disrupted platelet sample, but in any case is either a direct or indirect measurement of C4d deposited on the surfaces of platelets."

The Applicant submits that clear and sufficient guidance is provided in the specification for one of ordinary skill in the art to determine the metes and bounds of the claimed invention as recited in claim 1 and therefore, this rejection should not stand.

With regard to the term "greater quantities", the Applicant submits that claim 1 is amended as follows: "with the ~~greater~~ quantities of C4d associated with platelets obtained from the individual being higher as compared to quantities of C4d associated with platelets obtained from individuals not having systemic lupus erythematosus", and as amended, one of ordinary skill in the art would be reasonably apprised of the scope of the invention of claim 1 and thus, this rejection should not stand.

In regards to the assertion that claim 2 is vague and indefinite for reciting "C42b associated with platelets", the Applicant respectfully submits that the reasoning provided above herein for the recitation of the phrase "associated with" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 2 should not stand.

In regards to the assertion that claim 9 is vague and indefinite for reciting "C4d associated with platelets", the Applicant respectfully submits that the reasoning provided above herein for the recitation of the phrase "associated with" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 9 should not stand.

Relating to the recitation of "greater quantities" in claim 9, the Applicant respectfully submits that the reasoning provided above herein for the recitation of the phrase "greater quantities" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 9 should not stand.

Relating to the recitation of "complement C4d associated with platelets" in claim 10, the Applicant respectfully submits that the reasoning provided above herein for the recitation of the phrase "associated with" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 10 should not stand.

In regards to the assertion that claim 10 is indefinite for recitation of the term "greater quantities", the Applicant respectfully submits that the reasoning provided above herein for the recitation of the phrase "greater quantities" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 10 should not stand.

Relating to the recitation of "complement C4d associated with platelets" in claim 11, the Applicant respectfully submits that the reasoning provided above herein for the recitation of the

phrase "associated with" in claim 1, is equally applicable in this context. Based on this reasoning, the Applicant submits that this rejection of claim 11 should not stand.

Double Patenting Rejections

Claims 1, 3-5 and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-18 and 21 of U.S. Patent No. 7,390,631. The Applicant submits that a terminal disclaimer in compliance with 37 CFR 1.321 is filed herewith to overcome this rejection.

Claims 1, 3-5 and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U. S. Patent No. 7,361,517. The Applicant submits that a terminal disclaimer in compliance with 37 CFR 1.321 is filed herewith to overcome this rejection.

Claims 1, 3-5 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 8, 9, 15, 18-20, 24 and 26 of copending Application No. 10/866,509. The Applicant submits that a terminal disclaimer in compliance with 37 CFR 1.321 is filed herewith to overcome this rejection.

Claims 1, 3-5 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 10-13, 18 and 19 of copending Application No. 10/545,052. The Applicant submits that a terminal disclaimer in compliance with 37 CFR 1.321 is filed herewith to overcome this rejection.

Claim Rejections Under 35 U.S.C. 102

Claims 1, 3-5 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,390,631 to Ahearn ("Ahearn"). The Applicants respectfully traverse this rejection.

The Applicant submits that Ahearn relates to methods for diagnosing and monitoring systemic lupus erythematosus (SLE) or scleroderma by determining, in a blood sample from the individual being diagnosed or monitored, complement component C4d, and optionally complement receptor CR1, deposited on surfaces of red blood cells in the sample. There is nothing in Ahearn to teach or suggest the use of platelets instead of red blood cells in the method for diagnosing and monitoring. The Examiner asserts that it is reasonable within the context of the broad claim to interpret "associated" to encompass any and all complement pathway

component C4d that is present in the whole blood sample including those that are present in plasma and those deposited onto erythrocytes. The Applicant respectfully disagrees. As previously indicated, the term "associated with" is defined in the originally filed specification as follows.

> "For accuracy, the methods described herein measure C4d "associated with" platelets. The reason for this distinction arises from the fact that some methods, such as flow cytometry, measure C4d on the surface of intact platelets directly, while other methods quantitate surface C4d indirectly in a sample of disrupted platelets, and do not literally measure C4d on the surfaces of platelets. As such, as used herein, C4d is said to be "associated with" platelets, which means either C4d is on the surface of a platelet or it is present in a disrupted platelet sample, but in any case is either a direct or indirect measurement of C4d deposited on the surfaces of platelets."

The definition relates to the direct and indirect measurement of C4d deposited on the surfaces of platelets and does not teach or suggest the inclusion of measurements of C4d present in plasma and/or deposited onto erythrocytes.

Thus, the Applicant submits that the claimed invention as recited in independent claim 1 is distinguishable from Ahearn and therefore, this rejection should not stand.

The reasoning set forth above herein for independent claim 1 is equally applicable to independent claims 9, 10 and 11 which also recited the term "associated with". Thus, the Applicant submits that independent claims 9, 10 and 11 are also distinguishable from Ahearn and therefore, this rejection should not stand for these claims.

Moreover, the Applicant submits that dependent claims 3-5 and 12 depend from a patentably distinguishable base claim (i.e., independent claim 1, 9, 10 or 11) and therefore, these claims are also distinguishable from Ahearn and this rejection should not stand.

Claims 1, 3, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Assessment of Disease Activity and Impending Flare in Patients with Systemic Lupus Erythematosus, Arthritis and Rheumatism, Vol. 35, No. 9, September 1992 ("Buyon"). The Applicant respectfully traverses this rejection.

The Applicant submits that the reasoning provided above herein relating to the interpretation of the term "associated with" in independent claims 1, 9, 10 and 11 with respect to Ahearn is equally applicable in this context in regards to Buyon. Based on this reasoning, the Applicant submits that the specification as originally filed defines the term "associated with" to

include the direct and indirect measurement of C4d deposited on the surfaces of platelets and does not teach or suggest the inclusion of measurements of C4d present in plasma as disclosed in Buyon.

Thus, the Applicant submits that the claimed invention of independent claims 1, 9 and 10 is distinguishable from Buyon and therefore, this rejection should not stand.

Moreover, the Applicant submits that dependent claim 3 depends from a patentably distinguishable base claim (i.e., independent claim 1) and therefore, this dependent claim is also distinguishable from Buyon and this rejection of claim 3 should not stand.

Claim Rejections Under 35 U.S.C. 103

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buyon in view of A Flow Cytometric Assay for Measuring Complement Receptor 1 (CR1) and Complement Component C4d on Erythrocytes, Journal of Immunological Methods 142: 45-52, 1991 ("Freysdottir"). The Applicant respectfully traverses this rejection.

Dependent claims 4 and 5 depend from independent claim 1. For the reasons provided above herein, the Applicant submits that Buyon does not teach or suggest the claimed invention as recited in claim 1. Since claims 4 and 5 depend from claim 1, a patentable base claim, the Applicant submits that claims 4 and 5 are also patentable over Buyon.

Furthermore, the Applicant submits that Freysdottir does not teach or suggest the claimed invention of claim 1. Freysdottir relates to the development of a flow cytometric assay to measure complement receptor 1 (CR1) and complement fragments C3d and C4d on erythrocytes. Freysdottir does not teach or suggest a method for identifying SLE including the features of the method as recited in the claimed invention of claim 1. Further, Freysdottir does not mention identifying SLE in any context. The Applicant submits that claim 1 is distinguishable from and not obvious based on Freysdottir. Since dependent claims 4 and 5 depend from independent claim 1, a patentable base claim, the Applicant submits that claims 4 and 5 are also patentable over Freysdottir.

In considering the combination of Buyon and Freysdottir, the Applicant submits that there is nothing in either reference to suggest such combination. Further, the Applicant submits that these references could not be combined without the at least partial destruction of each reference. Thus, the Applicant submits that such combination is improper. However, even if

such combination were proper, the Applicant submits that these references still do not teach or suggest the claimed invention of claim 1. Neither Buyon nor Freysdottir teaches or discloses quantitating C4d associated with platelets (e.g., a direct or indirect measurement of C4d deposited on the surfaces of platelets). Buyon relates to plasma and Freysdottir relates to erythrocytes and therefore, Freysdottir does not overcome the shortcomings of Buyon.

Thus, the Applicant submits that independent claim 1 is patentable over Buyon, Freysdottir, or the combination thereof. Further, dependent claims 4 and 5 depend from a patentable base claim , i.e., independent claim 1, and therefore these claims are also patentable over Buyon, Freysdottir, or the combination thereof.

Claims 2, 6-8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahearn or Buyon in view of Freysdottir, in further view of Flow Cytometric Evaluation of Platelet Activation in Blood Collected Into EDTA vs. Diatube-H, American Journal of Hematology 50:40-45, 1995 ("Kuhne"). The Applicant respectfully traverses this rejection.

Dependent claims 2, 6-8, 13 and 14 depend from independent claim 1 or independent claim 11. For the reasons provided above herein, the Applicant submits that Ahearn does not teach or suggest the claimed invention as recited in claims 1 and 11. These reasons are equally applicable in this context. Since claims 2, 6-8, 13 and 14 depend from a patentable base claim, i.e., claim 1 or 11, the Applicant submits that claims 2, 6-8, 13 and 14 are also patentable over Ahearn.

For the reasons provided above herein, the Applicant submits that Buyon does not teach or suggest the claimed invention as recited in claims 1 and 11. These reasons are equally applicable in this context. Since claims 2, 6-8, 13 and 14 depend from a patentable base claim, i.e., claim 1 or 11, the Applicant submits that claims 2, 6-8, 13 and 14 are also patentable over Buyon.

For the reasons provided above herein, the Applicant submits that Freysdottir does not teach or suggest the claimed invention of claim 1. These reasons are equally applicable in this context. Since claims 2 and 6-8 depend from a patentable base claim, i.e., claim 1, the Applicant submits that claims 2 and 6-8 are also patentable over Freysdottir.

Further, the Applicant submits that Freysdottir does not teach or suggest the claimed invention of claim 11. Freysdottir does not teach or suggest a kit for use in identifying SLE including the features of the kit as recited in the claimed invention of claim 11. Further,

Freysdottir does not mention identifying SLE in any context. The Applicant submits that claim 11 is distinguishable from and not obvious based on Freysdottir. Since dependent claims 13 and 14 depend from independent claim 11, a patentable base claim, the Applicant submits that claims 13 and 14 are also patentable over Freysdottir.

The Applicant submits that Kuhne relates to the use of flow cytometry for measuring the amount of platelet cell surface antigen in whole blood samples. The Applicant submits that Kuhne does not teach or suggest the claimed invention of claims 1 and 11. There is nothing in Kuhne to teach or suggest a method or kit for identifying SLE including the features recited in the claimed invention of claims 1 and 11, respectively. Further, Kuhne does not mention identifying SLE in any context. The Applicant submits that claims 1 and 11 are distinguishable from and not obvious based on Kuhne. Since dependent claims 2, 6-8, 13 and 14 depend from a patentable base claim, i.e., claim 1 or 11, the Applicant submits that these claims are also patentable over Kuhne.

In considering the combination of Ahearn, Buyon, Freysdottir and Kuhne, the Applicant submits that there is nothing in any of these references to suggest such combination. Further, the Applicant submits that these references could not be combined without the at least partial destruction of each reference. Thus, the Applicant submits that such combination is improper. However, even if such combination were proper, the Applicant submits that these references still do not teach or suggest the claimed invention of claims 1 and 11. Neither Buyon nor Freysdottir teaches or discloses quantitating C4d associated with platelets (e.g., a direct or indirect measurement of C4d deposited on the surfaces of platelets), for use in identifying SLE in an individual. Ahearn and Buyon mention methods of diagnosing SLE only in the context of using C4d as markers that are present in plasma, not platelet as recited in the claimed invention. Freysdottir mentions erythrocytes and Kuhne mentions platelets, but only in the context of flow cytometry procedures and evaluations, not SLE diagnosis. Thus, there would be no reason to look to Freysdottir and Kuhne which relate to erythrocytes and platelets to modify the methods of Ahearn and Buyon which relate to plasma. Thus, the Applicant submits that Ahearn, Buyon, Freysdottir, Kuhne or combinations thereof, do not fairly suggest the claimed invention as recited in independent claims 1 and 11.

Further, because dependent claims 2, 6-8, 13 and 14 depend from a patentable base claim, i.e., independent claim 1 or 11, the Applicant submits that these claims are also patentable over Ahearn, Buyon, Freysdottir, Kuhne or combinations thereof.

CONCLUSION

The prior art references cited by the Examiner and relied upon, as well as the prior art references made of record but not relied upon have been carefully reviewed, and the Applicant submits that the claimed invention of claims 1-14 are distinguishable from and patentable based on these references. Thus, the Applicants submit that pending claims 1-14 are in condition for allowance and therefore, reconsideration of the claims and the prompt issuance of a notice of allowance is respectfully requested.

Respectfully submitted,

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